INFORMED CONSENT

Title: Quantitative assessment of the activation of brain areas with positive and negative emotional stimuli and its correlation with degrees of emotional disorder.

NCT number: not yet assigned

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INCOR IMAGES - Bazan y Bustos 132. La Rioja (5300)

Main investigator: Ruben Novoa, MD Head of Magnetic Resonance Imaging at Incor Images. rubennnovoa@gmail.com Tel: 3804509777

Collaborators: Graduates in production of Bioimages Maribel Oliva, Ivana Ceressa and Paolo Paez from the Magnetic Resonance Imaging Area of Incor Images.

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INCOR IMAGES - Bazan y Bustos 132. La Rioja (5300) Main researcher: Dr. Ruben Novoa, Head of Magnetic Resonance Imaging at Incor Images.

Volunteer name: …… You are being invited to participate in this medical research study. Before deciding whether to participate or not, you should know and understand this informed consent. Feel completely free to ask any questions you may have. Once you have understood the study and if you wish to participate, then you will be asked to sign this informed consent, a copy of which will be provided to you.

JUSTIFICATION FOR THE STUDY: Emotional deficits are part of different diseases. Different patients may have different emotional disorders that require personalized treatments for best results. The study of brain activity in volunteers without and with some degree of emotional deficit will allow a better understanding of the mechanisms that produce these alterations. This knowledge could help generate more effective personalized treatments for each patient.

STUDY OBJECTIVE: You are being invited to participate in a research study that aims to better understand the normal functioning of the brain in relation to emotions and what are the changes in this functioning in patients with emotional disorders.

BENEFITS OF THE STUDY: The study will help to have a better understanding of emotional disturbances and could be useful in generating personalized treatments. Personally, the Brain Functional Magnetic Resonance study is at no cost to you and will be delivered to your treating physician or directly to you if you prefer.

STUDY PROCEDURES: If you meet the conditions to participate in this protocol and agree to participate, the following procedures will be carried out:

1- You will be asked to complete a written questionnaire to evaluate if you do not have contraindications to perform a Functional Magnetic Resonance study.
2- You will be asked to answer a written questionnaire to evaluate your emotional state in general. These responses will remain anonymous and will only carry an internal identification number but not your personal data.
3- You will be given a Functional Magnetic Resonance exam. If you have already had an MRI previously for any other reason, the experience is the same, staying for about 20 minutes in the MRI equipment while the images are being taken. The difference is that this time two movies will be shown to you, asking you to pay attention to them and simply let the feelings that these movies produce in you flow. As in any MRI study, you will be asked not to move during the study.
4- No medication will be administered.
5- No radiological contrast material or any other substance will be injected.

6- The data obtained from your study will be included in the research work anonymously, they will only be related to a number assigned in the study but not to your name.

7- - The data obtained in the study will be stored anonymously and may be used for the development of future research.

RISKS ASSOCIATED WITH THE STUDY

By not using contrast media or medications, and having previously ruled out that you may have any contraindications to the performance of an MRI (such as having a pacemaker, aneurysm clips, cochlear implants or other incompatible artifacts), they have not been described risks for conducting this type of study.

CLARIFICATIONS

1- Your decision to participate in the study is completely voluntary.

2- There will be no unfavorable consequence for you, if you do not accept the invitation.

3- If you decide to participate in the study, you can withdraw at any time you wish, being able to inform or not the reasons for your decision.

4- You will not have to make any expenses during the study.

5- You will not receive payment for your participation.

6- During the course of the study, you may request updated information about it from the responsible researcher.

7- The information obtained in this study, used to identify each patient, will be kept strictly confidential by the group of researchers.

8- You also have access to INCOR's Ethics Committee in case you wish to clarify any doubts.

If you consider that you have already clarified all your doubts and questions about your participation in the study, if you wish, you can sign the following Informed Consent: I, …… I have read and understood the above information and my questions have been answered satisfactorily. I have been informed and understand that the data obtained in the study may be published or disseminated for scientific purposes, keeping my personal data anonymous. I agree to participate in this study. You will receive a signed and dated copy of this document.

Signature of participant or parent or guardian

Witness 1 ……

Witness 2 ……

Date

This part must be completed by the investigator (or his representative): I have explained to Mr. (a) ……. the Nature and Purposes of the Research, the risks and benefits of participating. I have answered his questions to the extent possible and asked if he has any questions. This protocol complies with and respects the ethical principles for medical research in human beings of the Declaration of Helsinki of the World Medical Association in its version of the year 2013. Once the question and answer session was over, this document was signed.

Investigator Signature

Date

REVOCATION OF CONSENT

Title: Quantitative assessment of the activation of brain areas with positive and negative emotional stimuli and its correlation with degrees of emotional disorder.

INCOR IMAGES - Bazan y Bustos 132. La Rioja (5300) Main Investigator: Ruben Novoa, MD,Head of Magnetic Resonance Imaging at Incor Images.
Participant name: …… In this way I wish to inform my decision to withdraw from this research protocol for the following reasons (optional):

If the patient so wishes, he may request that all the information that has been collected about him be given to him, on the occasion of his participation in this study.

Signature of participant or parent or guardian

Witness 1 ……
Witness 2 ……

Date

(It must be made in duplicate, leaving a copy in the possession of the patient)